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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,125	03/28/2001	Etsuya Matsutani	2556USOP	7053

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TAKEDA PHARMACEUTICALS NORTH AMERICA, INC
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EXAMINER	
RAWLINGS, STEPHEN L	
ART UNIT	**PAPER NUMBER**
1643	

DATE MAILED: 01/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 09/806,125	**Applicant(s)** MATSUTANI ET AL.	
	Examiner Stephen L. Rawlings, Ph.D.	**Art Unit** 1643	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 29 November 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on *29 November 2005*. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *12-17*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☒ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☒ Other: See Continuation Sheet.

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1643

Continuation of 5. Applicant's reply has overcome the following rejection(s): Entry of the amendment filed November 29, 2005, obviates the grounds of the rejections of claims 12-17 over the prior art of record; in addition, entry of the amendment obviates the grounds of rejection set forth in the preceding Office action under the judicially created doctrine of obviouness-type double patenting.

Continuation of 11. does NOT place the application in condition for allowance because: The amendment filed November 29, 2005, fails to obviate or render moot each of the grounds of rejection of the claims set forth in the preceding Office action mailed May 31, 2005. In particular, the amendment fails to obviate or render moot the grounds of the rejections of claims 12-17 over 35 U.S.C. 112, first paragraph, as failing to comply with the written description and/or enablement requirements. Applicant's request for reconsideration of the rejection of claims 12-14, 16 and 17, as failing to satisfy the written description requirment, has been carefully considered but is predicated upon entry and consideration of the executed declaration under 37 C.F.R. 1.132 filed December 2, 2005. The declaration has not been entered or considered because Appelant had failed to provide a showing of a good and sufficient reason why it it is necessary and was not earlier presented. Because the declaration has not been entered or considered, the traversal of the rejection of claims 12-14, 16, and 17 in Applicant's request for reconsideration, which is predicated upon its entry and consideration, is moot. Otherwise, it is noted that Applicant has provided in Appendix A, which is attached to the amendment filed November 29, 2005, disclosures showing the structures of various inhibitors. This evidence has been carefully considered but is not found sufficient to overcome the ground of rejection of claims 12-14, 16, and 17, as failing to comply with the written description requirement, set forth in the preceding Office action, as it fails to establish that the specification would reasonably convey to the skilled artisan that Applicant had possession of the claimed invention at the time the application was filed. The particular reasons that the specification is deemed insufficient to satisfy the written description requirement are set forth in the preceding Office actions. Applicant's arguments traversing the ground of rejection of claims 12-17, as lacking a reasonably enabling disclosure, have been carefully considered but not found persuasive. Applicant has argued a person skilled in the art would know that "a non-hormone dependent cancer (prostatic cancer) is caused by an increase in expression of a growth factor receptor in prostatic cancer cells" (page 7, paragraph 2, of the amendment). In reply, this argument does not address the issues of record; furthermore, Applicant has provided no factual evidence to support their assertion. As to Applicant's other argument, while the specification is deemed reasonably enabling for using a composition for repressing proliferation of hormone-dependent prostate cancer, said composition comprising the peptide of SEQ ID NO: 1, or a salt thereof, wherein the sixth amino acid residue is D-leucine and the ninth amino acid residue is proline-NH-C2H5, and the tyrosine kinase inhibitor PD153035, does not reasonably provide enablement for making and using a composition for suppressing the metastasis or recurrence of a cancer by retarding the transformation of a hormone-dependent cancer to a non-hormone dependent cancer or for preventing cancer, including prostatic cancer, ovarian cancer, cervical cancer, and breast cancer, wherein said composition comprises the peptide of SEQ ID NO: 1, or a salt thereof, wherein the sixth amino acid residue is D-leucine and the ninth amino acid residue is proline-NH-C2H5, and any tyrosine kinase inhibitor of a cell growth factor receptor possessing tyrosine kinase activity, including the tyrosine kinase inhibitor PD153035. The particular reasons that the specification is deemed insufficient to satisfy the enablement requirement are set forth in the preceding Office actions. Finaly, with regard to the objecton of claims 12-17, as being drawn in the alternative to the subject matter of a non-elected species of invention, Applicant has argued that the claims are directed to methods comprising treating with both a hormonal agent and cyproterone, not one or the other. In reply, the contrary to Applicant's assertion, the claims are drawn to a method comprsing administering a hormonal agent selected from the peptide of SEQ ID NO: 2 or a salt thereof and cyproterone acetate, that is a method comprising administering either the peptide or cyrproterone acetate. The correctness of this interpretation is evident given, for example, claims 12 and 13, which are now canceled, as well as by the original claims (e.g., claims 1-5). Claim 13 further limits claim 12 by reciting the hormonal agent is the peptide or an acetate thereof. In the response to the restriction of claims 1-11 set forth in the Office action mailed February 10, 2004, which was filed March 3, 2004, Applicant elected the species of invention, wherein said hormonal agent is the peptide of SEQ ID NO: 1, or a salt thereof, wherein the sixth amino acid residue is D-leucine and the ninth amino acid residue is proline-NH-C2H5 and said cell growth factor is EGF or a substance possessing substantially the same activity as EGF. To the extent that the claims read on a method comprising administering cyproterone, as opposed to the peptide, the claims are directed to a non-elected species of invention. It was proper to restrict the claims to the subject matter of the elected species of invention for examination purposes for the reasons provided in section 16 at page 10 of the preceding Office action, since Applicant received an action on the merits for the originally presented (i.e., elected) species of invention, which species of invention was constructively elected by original presentation for further prosecution on the merits. If, for argument's sake, the claims should be interpreted as a method comprising administering both the peptide and cyproterone, then, it is submitted the claims read on a non-elected invention, as the special technical feature of that invention would be administering not one or the other hormonal agent but both in combination with the tyrosine kinase inhibitor, whereas the special technical feature of the elected invention was administering a peptide alone in combination with the tyrosine kinase inhibitor.

Continuation of 13. Other: The declaration filed November 29, 2005, has not been entered or considered because it was not properly executed.

STEPHEN RAWLINGS